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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,892	11/13/2003	Pei-Yong Shi	454311-2231.1	1951

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EXAMINER	
SALVOZA, M FRANCO G	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/706,892	SHI ET AL.
	Examiner	Art Unit
	M. Franco Salvoza	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-94* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

After review of the previous Action, it was determined that upon further consideration that further restriction is appropriate for a thorough and complete examination. The Office regrets any inconvenience. The restriction set forth below replaces the previous one.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-17, 20, 21, 28-32, 45-69, 93 drawn to a reverse genetics system for screening and identifying antiflaviviral compounds, a recombinant plasmid, a cell line, a DNA molecule, classified in class 424, subclass 184.1.

II. Claims 2-17, 20, 21, 28-32, 45-69, 93 drawn to a reverse genetics system for screening and identifying attenuated flaviviral vaccines, a recombinant plasmid, a DNA molecule, a cell line, classified in class 424, subclass 184.1.

III. Claim 18, drawn to a method for preparing a fully infectious RNA transcript, classified in class 536, subclass 23.1.

IV. Claims 19, 22-27, drawn to a method for preparing a cell line, classified in class 435, subclass 325.

V. Claims 33, 39, 70-92 drawn to a method of identifying potential antiflaviviral chemotherapeutics, a high throughput assay for screening and a method for screening a plurality of compounds, and a composition, classified in class 424, subclass 184.1.

VI. Claims 34-38, drawn to a method of collecting and transmitting a dataset, classified in class 710, subclass 717.

VII. Claim 40, drawn to a method for administering the pharmaceutical composition, classified in class 424, subclass 184.1.

VIII. Claims 41, 42, drawn to a method for generating a potential attenuated WNV vaccine, classified in class 424, subclass 184.1.

IX. Claim 43, drawn to method of generating a live attenuated WNV lineage I virus vaccine, classified in class 424, subclass 184.1.

X. Claim 44, drawn to method of treating a flaviviral infection, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II identify separate products having distinct functions, distinct structures, and distinct physical, chemical and functional properties requiring separate searches of the prior art.

Inventions III, IV, V, VI, VII, VIII, IX, X and are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions all represent different methods, which variously utilize different reagents, have different method steps, and/or achieve different goals. References that teach one method would not necessary disclose the other methods.

Inventions I, II and Inventions III, VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a reverse genetics system comprising a cDNA clone or replicon can be used in materially different processes such as coding for materially different products such as specific peptide sequences or proteins in order to raise antibodies against them.

Inventions I, II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case cell lines can be used for other materially different purposes other than replicating the reverse genetics system such as generating proteins or specific enzymes in large quantities.

Invention V and Inventions VII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds comprising the inhibitor can be used in materially different methods such as a method for screening.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

If one of the following Inventions is elected, further election of species is required since the claims recite products having distinct functions, distinct structures, and distinct physical, chemical and functional properties requiring separate searches of the prior art.

I. If applicant elects this group, applicant is required to elect:

either a (a) cDNA clone (claim 3) or (b) lineage I WNV replicon (claim 4);

one reporter (as recited in claim 7 and 47 for example) and one promoter (as recited in in claim 13 (and if viral promoter is selected in claim 13, one kind of viral promoter as recited in claim 14 and 54)); one structural gene from claim 50.

II. If applicant elects this group, applicant is required to elect:

either a (a) cDNA clone (claim 3) or (b) lineage I WNV replicon (claim 4);

one reporter (as recited in claim 7 and 47 for example) and one promoter (as recited in in claim 13 (and if viral promoter is selected in claim 13, one kind of viral promoter as recited in claim 14 and 54)); one structural gene from claim 50.

IV. If applicant elects this group, applicant is required to elect:

one of the flaviviruses in claim 23.

V. If applicant elects this group, applicant is required to elect:

One of the cell types from claim 74;

One of the reporters from claim 77;

One of the cell types from claim 85;

One of the reporters from claim 88;

One of the flaviviruses from claim 89;

One of the flaviviruses from claim 90.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116. Amendments

submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Franco Salvoza
Patent Examiner

JAMES HOUSEL 1/23/06
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